REMARKS

Applicant requests reconsideration of the present application in view of the foregoing amendment and the discussion that follows. The status of the claims is as follows. Claims 1-70 were originally filed. Claims 1-5, 12, 17, 18, 20-24 and 71-98 are currently pending. Claims 26-70 were previously withdrawn from consideration and these claims were canceled previously without prejudice to Applicant's filing of divisional applications to what has been determined in a previous Office Action to be the separately patentable subject matter thereof. Claims 6-11, 13-16, 19 and 25 were also canceled previously. Claims 1 and 71 have been amended herein and Claims 99-102 have been added.

The Amendment

Claim 1 was amended to recite that the support is non-porous. Support therefor is in the specification, for example, page 11, line 21.

Claim 71 was amended in a manner similar to that for Claim 1. Claim 71 was also amended as suggested in the Office Action to recite that the ledge extends horizontally from the top edge of the well to an area adjacent a bottom edge of the at least one wall.

Claims 99-102 were added and find support in the specification, for example, original Claims 23, 78, 85, and 94, respectively.

Rejection under 35 U.S.C. §112

Applicant submits that the amendment to Claim 71 obviates the rejection of Claim 71 under the second paragraph of the above code section.

Rejection under 35 U.S.C. §102

Claims 1, 2, 5, 12, 20, and 24 were rejected under 35 U.S.C. 102(b) as being anticipated by Lennon, *et al.* (U.S. Patent No. 4,999,163) (Lennon). The reference discloses a disposable, pre-packaged device for conducting an immunoassay procedure that results in the production of separable liquid and solid phases. The device includes a cup having an inlet and presenting a liquid phase receiving chamber. An absorbent for liquid phase materials is in the chamber and a series of ribs hold the absorbent away from the walls of the chamber providing a breathing

space extending around the absorbent. A porous capture media element for capturing and displaying solid phase products of the procedure is disposed adjacent the inlet of the device in fluid communication with the absorbent so that in operation the absorbent promotes flow of liquid phase through the capture element. A lid element is mounted on the cup adjacent the inlet, and the lid and the cup are held together by welding of annular flanges. The lid element includes an elongated cylindrical member extending through the inlet and defining a throat for directing flow of liquid phase onto the capture media. The cylindrical member has an annular surface at its inner end for contacting the porous capture media and holding it in tight fluid communication with the absorbent. A vent hole is provided in the lid flange to facilitate venting of the breathing space. The vent hole and the throat opening are disposed in a single plane so that a single planar coil element may be used to keep out contamination during storage and shipment.

Lennon does not disclose or suggest the invention of Claim 1. The assay element 18 of Lennon, which is identified in the Office Action as a support, is porous. The support of Claim 1 is non-porous. Lennon's support must be porous in order to accomplish his assay. As stated in Lennon's disclosure (col. 3, lines 18-31), absorbent means are disposed in the chamber for promoting flow of liquid into the chamber and spacer means are provided in the chamber for holding the absorbent means away from the inner walls of the chamber to present a breathing space communicating with the inlet. The breathing space extends essentially entirely around the absorbent means to facilitate venting and thus flow of fluid into the absorbent during the conduct of the test procedure. The device preferably includes porous capture media means for capturing and displaying products of the procedure, such porous capture media means being disposed adjacent the inlet of the device and in fluid communication with the absorbent means.

Thus, the central theme of Lennon is to have liquid pass through a porous media being pulled therethrough by an absorbent plug in fluid communication with the porous media. Accordingly, a non-porous support would not work in the device and method of Lennon. Therefore, there would be no motivation for one skilled in the art to substitute a non-porous support for the porous support of the reference.

In the invention of Claim 1, the well is designed to contain fluid, not to allow fluid to pass through. As indicated in the present specification (page 9, lines 3-4), in

the present invention a volume of a fluid sample is contained in a well created by walls around the perimeter of a support such as a glass slide. In fact, one of the problems addressed by the present invention is that of liquid wicking out of the well of the device. As indicated in the present specification, loss of even small quantities of the sample can be detrimental to the accuracy of an assay and can also result in waste of sample, which is already in limited quantity. Wicking would not be a concern of Lennon because liquid placed in his well is drawn through the porous member into the absorbent material.

Lennon does not disclose or suggest the device of Claim 2 wherein the at least one wall is designed such that the corners thereof are radiused. There is no disclosure in Lennon regarding such a device.

Claims 71, 72, 73, 76, 79, 81, 82, 83, and 89-93 were rejected under 35 U.S.C. 102(b) as being anticipated by Chen, *et al.* (U.S. Patent No. 5,096,809) (Chen). Chen discloses a method for detecting analytes in samples of whole blood using solid-phase, permeable support assay devices. The whole blood assays require no steps or reagents other than those necessary to carry out the same analysis on plasma or serum using the devices. The color visualization of the analytical field on which the interpretation of the assay depends is not affected by the presence of intact erythrocytes or any degree of hemolysis in the blood sample.

Chen does not disclose or suggest the invention of Claim 71. The porous support 32 of Chen is, as indicated, porous. The support of Claim 71 is non-porous. Chen's support must be porous in order to accomplish his assay. As indicated in the reference, each of the openings 24 has a layer of porous material 32 across the bottom of the opening 24 and visible through the opening. This porous support 32 is located so that liquid flowing from the sample receiving means 26 through the openings 24 must pass through the portion of the porous support 32 visible through the openings 24. Located beneath the porous support 32 on the inside 20 of the housing 12 is absorbent material 34, which acts to draw fluid through the porous support 32.

Thus, the focus of Chen is to have liquid pass through the porous support being pulled therethrough by the absorbent material in fluid communication with the porous support. Accordingly, a non-porous support would not work in the device and

method of Chen. Therefore, there would be no motivation for one skilled in the art to substitute a non-porous support for the porous support of the reference.

In the invention of Claim 71, the well is designed to contain fluid, not to allow fluid to pass through. As mentioned above and as indicated in the present specification (page 9, lines 3-4), in the present invention a volume of a fluid sample is contained in a well created by walls around the perimeter of a support. In fact, one of the problems addressed by the present invention is that of liquid wicking out of the well of the device. As indicated in the present specification and above, loss of even small quantities of the sample can be detrimental to the accuracy of an assay and can also result in waste of sample, which is already in limited quantity. Wicking would not be a concern of Chen because liquid placed in his well is drawn through the porous member into the absorbent material.

Rejections under 35 U.S.C. §103

Claims 3, 4, 17, 18, 22, and 98 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lennon. The Office Action asserts that Lennon differs from the instant invention in failing to teach the specific dimensions recited in Claim 3 for the assay element 18 or the specific dimensions and angles recited in Claims 4, 17, 18, and 98. However, the Office Action contends that the optimum dimensions and angles required for each of the components in the assay device of Lennon for optimum assay results can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art.

Applicant respectfully traverses this ground of rejection. As Applicant indicated in the Specification (page 26, lines 19-25, and paragraph bridging pages 23 and 24), for reactions involving biopolymers particularly in the form of an array of biopolymers, a small quantity of sample is distributed over the surface of the support to which the biopolymers are attached. Applicant has discovered that, in situations where a small volume of liquid forms a thin layer above the surface of a substrate or support, which comprises a plurality or an array of biopolymers, wicking of liquid from the well may occur. The structural features of the devices of the present invention avoid such wicking. Accordingly, the present invention goes far beyond mere differences in size of an article of manufacture. The references do not teach or suggest the structural features set forth in the claims; nor do the references teach

the problem solved by the present invention. It has long been held that discovery of a problem is one consideration in determining the patentability of a claimed invention. *In re Atkinson*, 102 F.2d 882, 41 USPQ 308 (C.C.P.A. 1939); *In re Nomiya*, 509 F.2d 566, 184 USPQ 607 (C.C.P.A. 1969). Furthermore, as mentioned above, wicking would not be a concern of Lennon because liquid placed in his well is drawn through the porous member into the absorbent material.

Claim 21 was rejected under 35 U.S.C. 103(a) as being unpatentable over Lennon in view of Chen. The Office Action contends that the device of Lennon differs from the instant invention in failing to teach the use of polynucleotides as an analyte detection reagent in assay element 18. It would have been obvious to one of ordinary skill in the art, asserts the Office Action, to use polynucleotides, such as RNA or DNA, as taught by Chen in the assay element 18 of Lennon because Lennon is generic with respect to what assay reagents may be incorporated into assay element 18 and Chen shows that it is conventional in the art to use polynucleotide reagents in assay elements such as those disclosed in Lennon.

Without acquiescing in the above assertion, Applicant submits that Claim 21 is patentable over Lennon and Chen by virtue of its dependency from Claim 1.

Claims 74, 75, 77, 80, 84, 86, 87, 88, 96, and 97 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chen. The Office Action argues that Chen differs from the instant invention in failing to teach the dimensions recited in claim 97 for the porous support 32 or the specific dimensions and angles recited in claims 74, 75, 77, 87, 88, and 96. The Office Action further asserts that the device of Chen differs from the instant invention in the shape and thus number of walls forming the sample receiving region in Figure 2 of Chen as set forth in Claims 80, 84, and 86. However, contends the Office Action, the optimum dimensions and angles required for each of the components in the assay device of Chen for optimum assay results can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. With respect to Claims 80, 84, and 86, asserts the Office Action, since the criticality of the shape of the ledge and opening above the ledge and the number of walls forming the opening above the ledge set forth in Claims 80, 84, and 86 has not been established, the optimum shape of the ledge and opening above the ledge and the number of walls forming the opening above the ledge in the sample receiving region in Figure 2 of Chen can be determined by

routine experimentation and thus would have been obvious to one of ordinary skill in the art.

Applicant respectfully traverses this ground of rejection. As Applicant indicated in the Specification (page 26, lines 19-25, and paragraph bridging pages 23 and 24) and reiterated above, for reactions involving biopolymers particularly in the form of an array of biopolymers, a small quantity of sample is distributed over the surface of the support to which the biopolymers are attached. The methods should be carried out in a manner that minimizes or avoids loss of liquid in the well of the device. Applicant has discovered that, in situations where a small volume of liquid forms a thin layer above the surface of a substrate or support, which comprises a plurality or an array of biopolymers, wicking of liquid from the well may occur. The structural features of the devices of the present invention avoid such wicking. Accordingly, the present invention goes far beyond mere differences in size of an article of manufacture. The references do not teach or suggest the problem solved by the present invention and, thus, the references offer no teaching or suggestion regarding the structural features set forth in the present claims. Furthermore, as mentioned above, wicking would not be a concern of Chen because liquid placed in his well is drawn through the porous member into the absorbent material.

Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Lennon. The Office Action asserts that the device of Chen differs from the instant invention in failing to teach the use of a cover over the wells 24 but refers to the teachings of Lennon, specifically removable foil cover 46. It would have been obvious to one of ordinary skill in the art, contends the Office Action, to incorporate a removable foil cover, as taught by Lennon, into the device of Chen to cover the sample receiving region because such a cover provides the advantages of protecting the sample receiving region from contamination and being removable when the device of Chen is to be used.

Without acquiescing in the above assertion, Applicant submits that Claim 95 is patentable over Lennon and Chen by virtue of its dependency from Claim 71.

Allowable Subject Matter

Claims 23, 78, 85, and 94 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in an allowable independent

form. Applicant has provided new claims 99-102, which are based on Claims 23, 78, 85 and 94, respectively. Original Claims 23, 78, 85 and 94 were not canceled because they are dependent from Claim 1 or Claim 71, as the case may be, and these latter claims are patentable over the art.

Conclusion

Claims 1-5, 12, 17-18, 20-24, 71-98 and 99-102 satisfy the requirements of 35 U.S.C. §§112, 102 and 103. Allowance of the above-identified patent application, it is submitted, is in order.

Respectfully submitted,

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